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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,320	11/26/2001	Tcodulo Aves	06570/002002	1358
22511	7590	04/07/2004	EXAMINER	
OSHA NOVAK & MAY L.L.P. 1221 MCKINNEY STREET HOUSTON, TX 77010			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,320

Applicant(s)

A

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6, 8, 9, 10, 11-15, 17, 20 and 21 are rejected under 35

U.S.C. 102(b) as being anticipated by Fischell et al., 4,141,365.

Fischell et al. discloses a needle (10) having a shaft having a lumen extending from the proximal end of the needle shaft and terminating at an opening (16) on the top of the distal end of the needle shaft, wherein the cutting surface (14) is on the bottom of the hollow shaft of the needle.

As to claim 2, the cutting surface (14) is from the bottom of the distal end of the hollow shaft to the front of the distal end of the hollow shaft.

As to claim 3, the needle (10) is adapted to be used where the cutting surface is substantially parallel to the dural fibers.

As to claim 4, the sharpness of the cutting surface is considered to be, as measured by the grams of force required for the needle tip to puncture a sheet of two mil thick polyethylene, is from about 85 grams of force to about 100 grams of force.

As to claims 5, 6, 11, 12, the needle is adapted to used in the procedures claimed.

Art Unit: 1641

As to claim 9, the cutting surface (14) begins on the bottom of the distal end of the hollow shaft and ends on the front of the distal end of the hollow shaft.

As to claims 10, 17, 20 and 21, a solid rod is disclosed at (2), having a gripping means (26), as claimed.

As to claim 13, a beveled surface is disclosed at (14), see Figure 1a, wherein the beveled surface is rounded and extends from the distal end of the cutting surface on the bottom of the shaft to the opening of the lumen on the top of the shaft.

As to claim 14, the beveled surface has a radial length less than about 25% of the needle outside diameter.

As to claim 15, the cutting surface (14) has the shape of a hull and extends from the outer edge of the bottom of the needle shaft to the front of the distal end of the shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al., 4,141,365.

Fischell discloses the invention substantially as claimed, see above, except for the needle being about 12 gauge to about 16 gauge. Fischell teaches that the invention

Art Unit: 1641

has useage as means for implantation of an electrode-bearing lead in a body for electrical stimulation of the spinal cord, and has utility for other therapeutic application, and that modifications in light of the teachings may be made, see column 8, lines 35-42. Modifications of the dimensions of the device would have been obvious to one of ordinary skill in the art as necessary for application of the device in various body parts having a particular size.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al., 4,141,365, in view of Takai et al. 4,945,895. Fischell et al. discloses the invention substantially as claimed, see above, except for a camera inside the lumen of the needle.

Takai et al. discloses a fiber optic (30) inside a needle for visualization during surgery. The fiber optic is equivalent to a camera as claimed. It would have been obvious to provide the fiber optic in the lumen of the Fischell needle for visualization during various surgery as taught by Fischell.

Response to Arguments

Applicant's arguments filed January 9, 2004 have been fully considered but they are not persuasive.

Applicant argues on page 3 that the Fischell device has a point (14) designed to pierce tissue, in contrast to the separating/cutting design of the instant invention, and

Art Unit: 1641

thus Fischell neither discloses nor suggests a cutting surface on a bottom surface of a needle.

In response, Examiner emphasizes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Thus, Examiner reasserts that Fischell discloses a surface on a bottom surface of a needle and that the surface is capable of cutting.

Allowable Subject Matter

Claim 16 is allowed.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: a method of pushing a needle into the epidural space with a cutting surface of the needle substantially parallel to the dura fibers of the patient, wherein the needle comprises a straight cutting surface was not found in the prior art search.

Also, the combination of elements including a needle having a lumen that has an end on a top surface of the distal end of the needle, a stylet to fit inside the needle, wherein the needle has a cutting surface on a bottom surface of the needle, and a spinal needle to fit inside the needle, was not found in the prior art search.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/05/04